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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,655

08/16/2005

Sitke Aygen

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

12/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,655	<b>Applicant(s)</b> AYGEN, SITKE	
	<b>Examiner</b> PATRICIA C. MALLARI	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/15/07.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/19/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/24/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I in the reply filed on 11/15/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 6 and 7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim.

### ***Information Disclosure Statement***

The information disclosure statement filed 6/24/05 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Specifically, neither an explanation of relevance nor an English translation has been provided for the German Patent DE 4426204 A1. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Claim Objections***

Claims 1 and 3-5 are objected to because of the following informalities:

On lines 1-2 of claim 1, "the pancreas" should be replaced with "the pancreas of a subject".

On line 2 of claim 1, "the increase" should be replaced with "an increase".

On lines 2-3 of claim 1 "the exhaled air" should be replaced with "the exhaled air of the subject".

On lines 3-4 of claim 1, "intravenous administration of secretin" should be replaced with "intravenous administration of secretin to the subject".

On lines 4-5 of claim 1, "oral administration of <sup>13</sup>C-triglyceride" should be replaced with "oral administration of <sup>13</sup>C-triglyceride to the subject".

On line 3 of claim 3, "IRMS or NDIR" should be replaced with "isotope ratio mass spectrometry (IRMS) or non-dispersive infrared spectroscopy (NDIR)".

On line 1 of claim 4, "characterized in that" should be replaced with "wherein intravenous administration of secretin comprises administering".

On line 2 of claim 4, "1 U" should be replaced with "1 clinical unit (U)".

On line 3 of claim 4, "kg of body weight" should be replaced with "kilogram of the subject's body weight".

On line 3 of claim 4, "is administered" should be deleted.

On line 2 of claim 5, "claim 1" should be replaced with "claim 2" because claim 2 has sufficient antecedent basis for the limitation "the mixed triglyceride" and claim 1 does not.

On line 2 of claim 5, "characterized in that" should be replaced with "wherein oral administration of <sup>13</sup>C-triglyceride comprises administering".

On line 3 of claim 5, "is administered" should be deleted. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 recites, "A method for measuring the metabolism of the pancreas". However, neither the claim nor the specification clearly sets forth how the metabolism of the pancreas is measured. It is assumed, based on the language set forth in the specification and in claim 1, that the increase in  $^{13}\text{CO}_2$  is related to the measurement of the metabolism of the pancreas. However, neither the specification nor the claims clearly describe how the increase in  $^{13}\text{CO}_2$  and a measure of pancreatic metabolism are related, such that one of ordinary skill in the art would be able to make and/or use the claimed invention without undue burden.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, in the preamble, "A method for measuring the metabolism of the pancreas" but fails to set forth how the metabolism of the pancreas is measured. The body of claim 1 merely states, "the increase in  $^{13}\text{CO}_2$  in the exhaled air is determined before and after intravenous administration of secreting and before and after oral administration of a  $^{13}\text{C}$ -triglyceride. It is unclear how this is a method for measuring the metabolism of the pancreas, since the claim language fails to relate any step of the method to measuring the metabolism of the pancreas.

#### ***Allowable Subject Matter***

No statement of allowance is being issued at this time for claims 1-5 due to the multiple rejections under 35 U.S.C. 112, 1st and 2nd paragraphs. However, no prior art has been applied to claims. The description of the most relevant prior art follows.

"Exocrine pancreatic insufficiency: accuracy and clinical value of the uniformly labeled  $^{13}\text{C}$ -Hiolein breath test" by Lembcke et al. discloses a method for measuring pancreatic metabolism in a subject, wherein the increase of  $^{13}\text{CO}_2$  in the exhaled air of the subject is determined before and after oral administration of a  $^{13}\text{C}$ -triglyceride (see entire document, especially p. 670 of Lembcke). Secretin was also administered intravenously (see entire document, especially p. 670 of Lembcke). A lower  $^{13}\text{CO}_2$  response was indicative of lower pancreatic metabolism (see entire document,

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especially the abstract of Lembcke). Lembcke fails to teach determining the increase in  $^{13}\text{CO}_2$  before and after the administration of secretin, as claimed.

"A Mixed-Triglyceride Breath Test for Intraluminal Fat Digestive Activity" by Ghooos et al. discloses a method for measuring pancreatic metabolism in a subject, wherein the increase in of  $^{14}\text{CO}_2$  in the exhaled air of the subject is determined before and after oral administration of a  $^{14}\text{C}$ -triglyceride and during intravenous administration of secretin (see entire document, especially p.240 of Ghooos). A smaller increase in  $^{14}\text{CO}_2$  in the exhaled air indicated a lower pancreatic metabolism (see entire document, especially pp.241-242, 245, and 246 of Ghooos). While it would have been obvious to one of ordinary skill in the art to use a  $^{13}\text{C}$ -triglyceride in place of the  $^{14}\text{C}$ -triglyceride, as shown by Lembcke, the method of Ghooos, as modified, would still lack determining the increase of  $^{13}\text{CO}_2$  in exhaled air before and after the administration of secretin, as claimed.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication 2001/0021815 to Katzman et al. also discloses a method for measuring the metabolism of the pancreas of a subject, or pancreatic insufficiency, wherein the increase of  $^{13}\text{CO}_2$  in the exhaled air of the subject is determined before and after oral administration of a  $^{13}\text{C}$ -triglyceride (see entire

document, especially fig. 5; paragraph 14 of Katzman). Katzman makes no mention of secretin being administered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/  
Patent Examiner, Art Unit 3735



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